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30-H

July 11, 2005

Mark McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1282-P
PO Box 8016
Baltimore, MD 21244-8016

Re: Medicare Program CMS-1282-P: Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities for FY 2006

Dear Dr. McClellan:

Genentech, Inc is pleased to respond to the Centers for Medicare & Medicaid Services' (CMS') request for comments on the proposed rule entitled "Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities for FY 2006 CMS-1282-P)." Genentech is a leading biotechnology company, headquartered in South San Francisco, California. We currently market 14 products designed to treat patients with serious or unmet medical needs, ranging from cardiovascular disease to cancer.

Medicare policy relating to reimbursement of our products, in various care settings, directly impacts patient access to these life-saving therapies. We, therefore, are particularly interested in providing comments to Section IV of the fiscal year (FY) 2006 proposed rule regarding consolidated billing (CB) in skilled nursing facilities (SNFs). Genentech appreciates the opportunity to provide CMS with comments on this issue, and encourages the Agency to adopt our recommendation that Healthcare Common Procedure Coding System (HCPCS) code J9035, *Injection, Bevacizumab, per 10 mg*, be added to the list of items and services excluded from SNF CB.

Background

In the Balanced Budget Act of 1997 (BBA), Congress established a provision under the prospective payment system (PPS) for SNFs called "consolidated billing" that requires almost all services SNF residents receive be included in the prospective payment amount.[1] However, in subsequent legislation, Congress also recognized that a number of high-cost services not administered frequently in SNFs could have "devastating financial impacts" for these facilities because the cost of such services may greatly exceed the SNF's consolidated payment under the PPS.[2] By statute, such services are excluded from CB and are separately billable to a Medicare Part B carrier. Specifically, in Section 103 of the Balanced Budget Refinement Act of 1999 (BBRA), Congress identified a number of items and services within four categories—chemotherapy items, chemotherapy administration services, radioisotope services, and customized prosthetic devices—to be excluded from the list of services paid to the SNF under the PPS.[3] CMS updates the list of HCPCS codes that are subject to the CB provision of the SNF PPS on a quarterly basis, as needed, when temporary HCPCS codes are released. An update also is released annually to include new permanent HCPCS codes.

Section 103 of the BBRA also gives the Secretary "the authority to designate additional, individual services for exclusions within each of the specified service categories."[4] In CMS' final rule of July 31, 2000, the Agency indicates that any additional item or service (identified by HCPCS code) that it might designate for exclusion from the SNF consolidated billing list must: (a) fall within one of the four service categories specified in the BBRA; and (b) meet the same standards of high cost and low probability in the SNF setting.[5] CMS has interpreted its statutory authority to revise the list of codes on the SNF consolidated billing exceptions list in "response to changes of major significance that may occur over time (for example, the development of new medical technologies or other advances in the state of medical practice)."[6] Genentech supports this interpretation of CMS' statutory authority and encourages the Agency to use it to ensure Medicare beneficiaries' access to important therapies is not jeopardized in the SNF setting.

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[1] Balanced Budget Act of 1997 (BBA), Public Law 105-33, Section 4432(b), Social Security Act (SSA), Section 1888(e)(2)(A)(ii).

[2] BBRA Conference report indicates high-cost, low probability services are those "not typically administered in a SNF, or are exceptionally expensive, or are given as infusions, thus requiring special staff expertise to administer." (H.R. Conference Report No. 106—479 at 854.)

[3] Chemotherapy items (identified as of July 1, 1999, by HCPCS codes J9000-J9020; J9040-J9151, J9170-J9185; J9200-J9201; J9206-J9208; J9211; J9230-J9245; and J9265-J9600, and as subsequently modified by the Secretary..." (SSA, Section 1888(e)(2)(A)(iii)(II)).

[4] Balanced Budget Refinement Act of 1999 (BBRA), Public Law 106-113, Section 113, Appendix F, SSA, Section 1888(e)(2)(A)(iii).

[5] 65 *Federal Register* 46790.

[6] 65 *Federal Register* 46791.

HCPCS J9035, *Bevacizumab 10mg*, Should Be Added to SNF CB Exceptions List

Genentech is particularly concerned that HCPCS code J9035, *Injection, Bevacizumab, per 10mg*, used to describe our chemotherapeutic product, Avastin™, is not listed on the SNF CB exceptions list. Avastin™ is the first anti-angiogenic clinically proven to extend survival for first-line treatment of metastatic colorectal cancer, a condition that affects a significant population of Medicare beneficiaries.[7] According to internal sales data, approximately 0.04 percent of Avastin™ sales occur in the SNF.[8] Because Avastin™ is a newly developed biologic, the cost of treatment with the product may deter use in SNFs. Genentech believes that Avastin™ is exactly the type of product Congress intended to exclude from the SNF CB exceptions list.

In addition, other chemotherapeutic products, particularly those for the treatment of colorectal cancer, are listed on the SNF CB exceptions list. Specifically, J9055, *Injection, Cetuximab, per 10 mg* (Erbitux™), is used to shrink and delay tumor growth in some patients with colorectal cancer. No clear reason exists as to why a therapy like J9055 is listed on the SNF CB exceptions list and J9035 is not. As such, Genentech feels strongly that Avastin™ meets the qualifications described above for an item or service to be excluded from the SNF CB list. Genentech urges CMS to add J9035, *Injection, Bevacizumab, per 10mg*, to the list of HCPCS codes excluded from SNF CB in the SNF PPS Final Rule for FY 2006.

Conclusion

Genentech thanks CMS for the opportunity to submit comments to the consolidated billing section of the SNF PPS FY 2006 proposed rule and urges CMS to fulfill Congressional intent by ensuring that SNF patients have access to needed medical therapies chosen in consultation with their physician. As such, we encourage the Agency to include new high cost, low use chemotherapy products such as J9035, *Bevacizumab, 10 mg*, to the consolidate billings exceptions list to receive separate payment in the SNF setting. Please do not hesitate to contact me directly at (202) 296-7272 if you have any questions about our comments or need additional information.

Sincerely,

Walter Moore
Vice President, Government Affairs
Genentech, Inc.

[7] www.avastin.com. Accessed June 20, 2005.
[8] Percentage based on Genentech sales data from January 2005 through June 2005.

National Hospice and Palliative Care Organization

31-H

July12, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1282-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: Comments on the proposed rules regarding the *Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities for FY 2006*

To Whom It May Concern:

The National Hospice & Palliative Care Organization (NHPCO) is the oldest and largest nonprofit membership organization representing hospice and palliative care programs and professionals in the United States. The organization is committed to improving end-of-life care and expanding access to hospice care with the goal of profoundly enhancing quality of life for people dying in America and their loved ones.

Hospice providers have been partnering with Nursing Facilities to provide quality end-of-life care to the frail elderly. NHPCO appreciates the opportunity to make comments on the proposed rules regarding the *Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities for FY 2006*, published in the Federal Register on May 19, 2005. Comments will be limited to issues in Section VI regarding the qualifying three-day inpatient hospital stay requirement.

CMS Hospice policy staff have made the determination that if a beneficiary receives Hospice General Inpatient level of care for three days, in a facility licensed as a hospital, the beneficiary meets the eligibility criteria for the Skilled Nursing Home Benefit. In this case, the licensure of the facility was the determining factor, rather than the level of care, because such services, if provided in a free-standing hospice or skilled nursing facility with 24 hour RN coverage would not meet the three-day threshold.

NHPCO has questioned this interpretation for the same reasons that have been described in Section VI, as to whether care provided in the hospital while the beneficiary is under observation or in the emergency room meets the intended medical threshold of need for the three day requirement. When the Hospice General Inpatient level of care is provided in a hospital, the stay is billed by hospice, not by the hospital, just as it is when those same services are provided in a free-standing hospice or skilled nursing facility with 24 hour RN coverage.

Thank you for considering our input on this issue.

Sincerely,

J. Donald Schumacher
President and CEO

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July 7, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: File Code CMS-1282-P
P.O. Box 8016
Baltimore, MD 21244-8016

Comments to the proposed rule published in the May 19, 2005 Federal Register

We appreciate the opportunity to comment on the proposed rule to update the payment rates in the Medicare Skilled Nursing Facility (SNF) Prospective Payment System (PPS) for FY 2006 and refinements to the RUG-III case-mix classification system.

The Kansas Health Care Association is the largest long-term care trade association in Kansas. We represent over 200 long-term care providers including long-term care units of hospitals, skilled nursing facilities and nursing facilities. On behalf of our membership, owners and administrators who participate in the Medicare and Medicaid programs, we submit the following comments relative to the "Proposed Refinements to the Case-Mix Classification System". Our comments and concerns center around changes to the current system re: the **look-back period, use of grace days, and projecting therapy minutes**. We believe that the elimination of the look-back period, grace days and estimated therapy minutes from the RAI Manual will adversely affect the quality of services to the post-acute-stay Medicare covered patient. Many of our providers deliver services in rural Kansas. We believe these changes could also reduce access to SNF services in rural areas of our state.

1. **The Look-Back Period should not be eliminated from the RAI Manual**

Our providers currently utilize the look-back period in order to determine the appropriate RUG classification of a SNF patient so that the patient will receive quality care and an adequate plan of treatment. If this look-back period is eliminated, we believe that the SNF will still provide the same care to the Medicare Part A patient however the provider will be paid substantially less in many circumstances. We believe that many patients who are transferred from hospitals to skilled nursing facilities will not be allowed to use one of the new upper nine RUG-53 groups because of lack of data to properly code patients at the extensive services level.

2. **The Grace Day Period should not be reduced or eliminated, specifically for the 5-day PPS MDS Assessment**

We believe that reducing or eliminating the grace day period, which is used to set the assessment reference date, would have a negative impact on patient care. We believe Grace Days allow for an adequate evaluation of therapy services to generate the best outcome for the patient. In order for a patient to be assessed higher than a Rehab Medium, the patient will have to be treated on all of the first 5 days in the SNF, including weekends, if grace days are eliminated. We believe this will restrict the Medicare patients access to Medicare Part A covered benefits in rural Kansas where therapists availability are already limited.

3. **Projection of anticipated therapy services during the 5-day PPS assessment should not be eliminated**

We believe that SNF providers act in the best interests of their patients when they project anticipated therapy services after the needs of the patient have been assessed and a rehab plan developed. We believe that again with therapists in short supply in rural areas of our state, that eliminating projection of therapy services is not in the patients best interest. We believe that any situations where estimated therapy is or has been overstated, should be dealt with on an individual basis.

On behalf of our membership in the state of Kansas, we respectfully submit our comments. If you have any questions please contact Nancy Pierce at the Kansas Health Care Association at 785-267-6003.

Sincerely,

Linda Berndt
Executive President, Kansas Health Care Association

33-H

Health Management Of Kansas, Inc.

Windsor Place

Offices: 2921 W. First Coffeyville, KS 67337 620-251-5190

DEPARTMENT OF HEALTH AND HUMAN RESOURCES
Centers for Medicare and Medicaid Services

File Code CMS-1282-P
July 7, 2005

TO WHOM IT MAY CONCERN:

Thank you for the opportunity to respond to proposed changes in the Medicare Prospective Payment System for the 2006 fiscal year. The following comments are relative to "Proposed Refinements to the Case-Mix Classification System".

The comments herein are specific to the proposed possible modifications to the Resident Assessment Instrument (RAI) Manual. We have significant concerns about each of the modifications to the current system including the look-back period, the use of grace days and projecting therapy minutes. The elimination of the look-back period, grace days and estimated therapy minutes from the RAI Manual will be discriminatory toward all residents in rural America in accessing quality skilled nursing facility services.

Look-Back Period:

The look-back period as it is currently implemented allows the facility to "look back" into the hospital stay of any Medicare eligible beneficiary to gather certain information pertinent to level of care necessary once the patient has admitted to the skilled nursing facility. The accumulation of this data is necessary in order to plan for the provision of the appropriate care as well as to determine the appropriate RUG group. As is stated in the SNF PPS final rule, the characteristic tendency for an SNF resident's condition to be at its most unstable and intensive state at the out set of the SNF stay," requires the SNF to commit its greatest amount of resources to the care of the post acute patient within the first few days after admission to the SNF.

Removing the look back period will greatly impact the SNFs ability to admit and care for those post acute patients requiring a SNF level of care. This action will also greatly impact the quality of care provided to the patient because of the inappropriate reduction of reimbursement necessary to provide the resources necessary to provide the quality of SNF care the beneficiary deserves.

for Private Nursing Homes. Are all of the nursing homes reflected in the Private Nursing Home indexes providers of skilled nursing care? Since labor and related costs make up a majority of the cost in a skilled nursing facility, it is a concern that the increasing labor costs SNFs have experienced over recent years may not be appropriately recognized in the factors being utilized. Again, it seems utilization of cost data provided
in the SNF Medicare cost reports could be utilized to provide more accurate information for skilled nursing facility market basket adjustments.

Proposed Refinements to the Case Mix Classification System – Federal Register Page 29080

Look Back Period

There are four clinical services that were highlighted on page 29080 as special services that utilize the that utilize the look back period: "... four items contained in the Special Services section of the MDS (P1a – IV medications, suctioning, tracheostomy care, and use of a ventilator / respirator) that serve to classify residents into Extensive Care, the category used for most medically complex SNF patients under the RUG-III classification system." Patients receiving these treatments are clinically unstable upon entering a skilled nursing facility setting.

Often patients are admitted to a skilled nursing facility directly from hospital ICU, rather than being placed in a hospital step down unit. Many patients enter a skilled nursing facility shortly after surgeries. Although patients entering a skilled nursing facility may not continue to utilize equipment available in a hospital setting and they may not continue with all of the procedures provided while in a hospital setting, these patients require extensive monitoring, observation, assessment of medical conditions, and follow up after the hospital discharge. It is important to include the look back period, to capture the extensive services that continue for these higher acuity patients.

Grace Day Period

Residents that require ultra high or very high rehabilitation can not always get the five days and 500 to 720+ minutes of rehabilitation in the initial five day assessment, without the use of grace days. An example would be of a patient that enters a SNF on a Wednesday. If the facility does not provide rehabilitation on Sunday's, the patient would not be able to receive the five days of therapy required to place them in a RU or RV RUGs level. When services are provided in this example the facility will not be reimbursed for the care they delivered without the grace period.

Concurrent Therapy – Federal Register Pages 29082 - 29083

In the discussion of concurrent therapy on page 29083 it is stated "we acknowledge that concurrent therapy can have a legitimate place in the spectrum of care options available to the therapists treating Medicare beneficiaries, as long as its use is driven by valid clinical considerations." There must always be a clinical consideration to provide therapy in a

in hospitals. The hospital stay preceding a SNF stay was intended to ensure the Part A beneficiary in a SNF was in need of skilled care not custodial care.

A distinction has been made between observation services and emergency room services in section VI on page 29099: "(Medicare Benefit Policy Manual), Chapter 6 (Hospital Services Covered Under Part B), section 70.4 (Outpatient Observation Services) in which a patient who needs more care than can be provided in an emergency room is moved from the emergency room, placed in a hospital bed in the appropriate hospital unit and monitored by the unit nursing and physician staff." Although a patient in an observation status is considered outpatient for hospital billing purposes, by the definition above the observation patients are in need of a greater level of care than patients remaining in the emergency room.

The hospital observation period, prior to an inpatient admission, should be combined with the hospital inpatient stay, to meet the 3-day hospital stay requirement necessary to qualify a beneficiary for Medicare Part A services in a skilled nursing facility. Hospitals are acute care settings. Patients are being observed while in an observation status, as well as after they are formally admitted as an inpatient. If it is determined a patient needs to be admitted after an observation period, the patient is in need of professional care, not being prepared for a custodial setting.

In addition to the three day qualifying hospital stay a Medicare beneficiary must have a physician certify the need for daily skilled care, for a beneficiary to receive Part A coverage in a skilled nursing facility. When the daily skilled services end, the Medicare Part A coverage also ends. Medicare Part A is not responsible for custodial care in a skilled nursing facility.

Thank you for your considerations of these comments. If you should have questions concerning these comments you can contact me at (540) 776-7535 or at the address below.

Sincerely,

Carol R Kroboth

Carol R. Kroboth
Vice President of Reimbursement
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July 11, 2005

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Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
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Washington, D.C. 20201

Attn: CMS-1282-P

Dear Mr. McClennan:

Thank you for the opportunity to offer comments on CMS-1282-P, Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities for FY 2006.

My name is Richard Bane, and I am an independent skilled nursing provider and owner in Essex County, MA. I operate four skilled nursing facilities, comprising 375 skilled nursing beds and in that capacity, I employ over 400 committed staff members. I am a second-generation owner and operator, and have been in this profession since 1985. I am not a corporate chain, and run a hands-on, closely managed operation. My facilities score consistently well in all quality measures and I am proud that our facilities are reputed to be the quality skilled nursing facilities of our region.

The proposed revisions CMS-1282-P will have a highly significant and highly negative impact to our quality operation. Specifically, I refer to the Proposed Revisions to the SNF PPS Labor Market Areas. By using the revised definitions for MSA's using the Core Based Statistical Areas, our local geography, therein defined as Essex County, will be segregated from what was previously Greater Boston. If you are not familiar with the geography of our area, my four facilities are all within a 14-mile radius of Logan Airport in downtown Boston. Essex County is located north of Greater Boston, and my facilities are located in southern Essex County, immediately abutting greater Boston urban area. In fact many of my employees live in the Greater Boston area, as opposed to Essex County. The actual impact of the new definition is not at all reflective of the actual wages for my facilities. If the new definition

is implemented, my facilities would experience a 5.55% DECREASE in reimbursement, which calculates to nearly $18 per day. This decrease is DRAMATIC and not sustainable or feasible economically.

I have spoken and met with my colleagues in the immediate area, all of who share my fear and dissatisfaction. While only informal, the providers in our area (Essex County) report that if the revision is implemented as proposed, in our area alone, the loss of reimbursement could translate to over 70 jobs.

Given this dramatic, negative impact, I would respectfully suggest that CMS should not proceed with the OMBA CBSA designations at this time. Instead it should first develop and implement a SNF specific wage index that would allow the payment system to more accurately reflect differences in area wage levels and would allow SNFs to request reclassification to alternate, more appropriate local market designations. CMS should also implement provisions that would establish a "rural" floor similar to the inpatient hospital PPS to deal with budget neutrality created anomalies in the SNF PPS. It is my understanding that the definitions being contemplated are based on hospital based wage designations. SNF's are very different than hospitals. Many of our staff are drawn from broader geographies, in particular to our facilities, we draw directly from Greater Boston urban areas. Using Essex County hospital based wage designations is not at all reflective of the reality of staffing our nursing homes.

If CMS does not see fit to amend the definitions, at a minimum, CMS should develop and implement an appropriate multi-year phase-in plan that would allow SNF's to make appropriate adjustments in their operations, particularly for those SNF's such as ours, that are most dramatically affected by the proposed changes. In addition to a phase-in of the OMB CBSA wage area designations, the phase-in should include the development and implementation of a SNF-specific area wage index, the establishment of a methodology in the SNF PPS for SNFs to request reclassification to alternate more appropriate local market areas, and the establishment of a methodology in the SNF PPS to establish a "rural" floor for the wage index. The use of such a "transition period" is absolutely essential for quality operations like ours to be able to provide the level of services and customer satisfaction that we are so proud of.

In summary, I would like to comment that there be specific revisions to the Proposed Rule as follows:

- CMS should proceed to develop and apply a SNF-specific area wage index, effective no later than FY 2007, and should immediately request the resources necessary to accomplish this;

- CMS should cease depriving SNFs of the ability, enjoyed by the hospitals, to have reclassifications to more appropriate indices, by developing the SNF-specific area wage index required by Congress as the basis of geographic reclassification for SNFs;

- Concurrent with the development of a SNF specific wage index, CMS should set in place the procedures for SNF geographic reclassification;

- CMS should not apply the OMBA CBSA designations to SNF since it does not have the authority to do so under the SNF PPS enabling legislation, the Balanced Budget Act of 1997 (BBA); and

- If CMS takes the position that it has the authority to apply the OMB CBSA area wage designations, CMS should develop and implement the four-year phase-in as outlined by AHCA in order to allow SNF's to make appropriate adjustments in their operations, particularly those SNF's that are most dramatically affected by the proposed changes.

Once again, thank you for the opportunity to present comment on CMS-1282-P. If promulgated without revision, the Rule will have a major detrimental impact on the wonderful quality facilities which we are so proud to operate. If you would like additional information, or would like to speak to me directly, please feel free to contact me directly.

Thank you.

Respectfully Yours,

Richard C. Bane
Bane Care Management LLC
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37-H

July 6, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: **Comments on Proposed Rule**
Medicare Program; Prospective Payment System &
Consolidated Billing for Skilled Nursing Facilities for FY 2006
File Code CMS-1282-P

Centers for Medicare and Medicaid Services:

The Centers for Medicare and Medicaid Services is proposing refinements to the Resource Utilization Groups used to determine payments for Medicare beneficiaries in skilled nursing facilities. Enclosed are one original and two copies of my comments related to the proposed rule published in the Federal Register May 19, 2005, (70 FR 29070). The proposed rule establishes the payment rates that will be used for fiscal year 2006, which begins October 1, 2005.

Comments Related To Proposed Refinements to the Case-Mix Classification System:

The proposed refinements to the case-mix classification system discussed in this section of the rule will reduce the aggregate Medicare payment to skilled nursing facilities under the 53-group RUG-III system when compared to the 44-group RUG-III system. The total reduction in aggregate Medicare payment to the fifty-five Skilled Healthcare LLC facilities will be approximately ten million dollars. The removal of the payment adjustments for the complex medical and rehabilitation groups account for nine million of the total ten million dollar reduction in aggregate Medicare payment to the fifty-five Skilled Healthcare, LLC facilities. The proposed Federal per diems for the new Rehabilitation plus Extensive RUG-III groups do not create a distributional payment hierarchy. Three of the nine highest Federal per diems are paid to old Rehabilitation Ultra High RUG-III groups. The effect of the increased number of groups and changes in the case-mix indexes should be distributional. The relative weights assigned to each RUG-III group should shift so that the proposed new Rehabilitation plus Extensive groups should have the highest payment and the payment for the old RUG-III groups should decrease proportionally.

Skilled Healthcare, LLC | 27442 Portola Parkway, Suite 200 | Foothill Ranch, CA 92610 T: 949-282-5800 F: 949-282-5859

Comments Related To Implementation Issues:

Revising the MDS Manual to eliminate the grace day period for the initial 5-day PPS assessment will diminish the flexibility of therapists to base their care plan on the readiness of residents for a therapy treatment. In a situation where a medically complex resident is admitted in an unstable condition, therapy services may not be tolerated until the resident's condition stabilizes on day six or seven of the stay. The therapy treatments provided on day six or seven would not be captured on a strict 5-day PPS assessment. In addition, revising the MDS Manual to eliminate the grace day period for the initial 5-day PPS assessment will result in less accurate MDS assessments. It will minimize the identification of clinical trigger items on the MDS that would impact individualized care planning. A beneficiary who receives intravenous medications, oxygen, respiratory treatments or rehabilitation services a day after the assessment reference date is grouped into a low clinically complex RUG-III category. Allowing no grace days means this complex services that was just recently provided will not be coded on the MDS. As a result of this, unique individualized care planning would be at a minimum. Intensity of rehabilitation treatments is influenced by a resident's clinical needs, co-morbidities, patient tolerance, and individualized goals.

Revising the MDS Manual to eliminate the 5-day PPS assessment of anticipated therapy will negatively impact residents needing therapy during the first fourteen days of their stay. Newly admitted residents do not always have physician orders for therapy. Eliminating anticipated therapy will deprive patients of receiving adequate therapy services needed for their immediate recovery. Elimination of anticipated therapy allows no flexibility for newly admitted patients to participate in therapy when clinically indicated. Beneficiaries will end up defaulting on a lower rehabilitation RUG category solely because of limited endurance during the first few days. This proposed rule discriminates patients in receiving therapy based on performance level on admits. This proposed rule also does not allow patients to have a chance to get adjusted to skilled nursing facility care prior to initiating therapy.

Eliminating the MDS 14-day look-back provision will result in residents being classified into inappropriate RUG-III categories and result in inaccurate payments to skilled nursing facilities. If services provided during the qualifying inpatient hospital stay are not captured on the 5-day MDS assessment, residents will be assigned to less clinically complex RUG-III categories. If the 14-day look-back period is eliminated, intravenous drugs and ventilator care should not be the only isolated criteria to qualify for extensive services. Stage three and four should be added as criteria for the Extensive Services RUG-III category. If the 14-day look-back period is eliminated, MDS criteria for significant change should also be revised to allow the provider to perform assessments anytime to classify to a higher RUG. The current criterion for significant

change involves two significant declines or improvement on patient's functioning that is not self-limiting. CMS should then allow flexibility in performing a significant change of condition assessment. CMS should refine the resident assessment instrument guidelines on significant change on MDS.

Comments on Qualifying Three-Day Inpatient Hospital Stay Requirement

The criteria for admission to a skilled nursing facility should be based on clinical criteria rather than a qualifying three-day inpatient hospital stay. Many Medicare beneficiaries could be referred directly to a skilled nursing facility following observation days and not be admitted inpatient to a hospital. If patients are directly referred to a skilled nursing facility, they can immediately receive skilled services, such as rehabilitation or continuing intravenous drug therapy, instead of being admitted inpatient to a hospital. This reduces the cost to the Medicare program, provides care in a more appropriate skilled nursing setting, and will result in a better outcome for the patient.

Comments on Consolidated Billing

The Medicare program and beneficiaries would benefit from adding service codes that qualify for exclusion to consolidated billing. A skilled nursing facility would be able to care for more patients needing chemotherapy. Some but not all of the medications that could be excluded from consolidated billing are: Procrit, Barium Swallow, Peritoneal Dialysis, Epogen, and Lovenox.

Thank you for allowing input into the proposed rule. We take pride in caring for higher acuity patients and we believe our comments and suggestions above would not only be beneficial to other Medicare SNF recipients, but the entire system that intends to move patients to a lower level of service more efficiently and safely.

Sincerely,

Jose Lynch
President
Skilled Healthcare LLC